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Compliance and Inspections

Revision of section 6 of the “Functional specifications for the EU portal and EU database to be audited - EMA/42176/2014” setting out features to support making information public

Draft reviewed with the EU clinical trial information system expert group as section 5 of proposal for an addendum, on transparency, to the “Functional specifications for the EU portal and EU database to be audited - EMA/42176/2014”	8 December 2014
Consultation with the MS for release for public consultation	9 December 2014 - 13 January 2015
Consultation with the European Commission for release for public consultation	9 December 2014 – 13 January 2015
Start of public consultation	21 January 2015
End of consultation (deadline for comments)	18 February 2015
Consultation of the final document by the European Commission	5 March 2015
Consultation of the final document by the Member States	2 March 2015
Endorsement by European Medicines Agency Management Board	19 March 2015
Sign off by the Deputy Executive Director	10 April 2015

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Wording to be added to section 6 of the "Functional specifications for the EU portal and EU database to be audited – EMA/42176/2014" prepared in accordance with Article 82 (1) of the clinical trial Regulation (EU) 536/2014:

6. Functional specifications to be audited (addendum)

The functional specifications of the EU portal and the EU database and associated workspace are outlined below and are considered necessary to enable the EU portal and the EU database to be fully functional.

In accordance with the Regulation, the EU database shall be publicly accessible unless, for all or part of the data and information contained therein, confidentiality is justified on any of the grounds outlined in Article 81(4).

Table 2 section 4.3 sets out the technical features to support publication of the information on clinical trials. The rules and criteria on what data and documents are to be made public, and on the timing of that publication, will be included in an appendix to these functional specifications. That appendix will be prepared following review of the responses to the public consultation that has taken place (21 January until 18 February 2015) and preparation and agreement of the rules and criteria by the Agency with the EU clinical trial information system expert group in collaboration with the Member States and the European Commission. The final text will be submitted for endorsement to the EMA Management Board and published following their endorsement and sign-off by the Agency Deputy Executive Director. This process should be completed by October 2015.

In addition to the functionalities outlined in this document, system performance, scalability and security are to be audited taking into account the need to support multiple users and an increase in volume of data over time.

Additional requirements to be made available in the workspace but outside of the scope of the functional specifications and audit as described in Article 82 are provided in annex 1 for information.

The following text, setting out high level technical features to support publication of the information on clinical trials, is added to table 2 section 4.3 of the previously published functional specifications:

4.3	Publication of CT data and information	The clinical trial data and information is to be made publicly available through a publication module of the database according to detailed rules to be defined taking into consideration the workflow of the trial. The rules are to be automated and implemented through the publication module of the database. The publication of clinical trial related documents and/or information will be an automatic process based on technical features set out here in section 4.3 and operated in accordance with predefined rules and criteria for publication, to be included as an appendix to this document. The rules and criteria for publication will be defined in such a way that in general manual intervention is not required. A manual override will be made available to enable publication in exceptional circumstances where an overriding public interest applies, as provided in the Regulation. The override may also be used to remediate errors where an item is required to be removed from the public domain for example when information has been published contrary to the established rules, or where data processing errors have occurred. The system should identify all data and documents in the EU database regarding their public or non-public status and any timeframe/event to trigger that publication, and include the necessary rules to ensure their public availability at the required time. For each data field (or set of related fields) or document the system will have metadata and rules to support their publication status and timing publication. The system should display the current and anticipated public status and timing of publication of each field and document. This information should be clearly flagged to sponsors, Member States and public users, alongside the relevant documents and data of each clinical trial. For each of these sets of information the database will have a structure to contain a document (or data such as names and addresses in the case of the investigator/trial sites list, sponsors etc.), but the content of the related documents should be defined outside of the design of the database and taking into account whether or not the information should be made public. The appropriate expert group of the EU should develop guidance and/or templates for the content of documents to be included in the database. The IMPD should be structured to enable each section (Q, S, E) to be separate and have different publication rules applied to each. The protocol synopsis and protocol should be separate and have different publication rules applied to each. The application form, and related assessment and conclusion on parts I and II will contain questions, and their corresponding answers, that

		will provide data points on which to base certain of the publication rules, which are not driven by other actions or data in the database. These questions (to be adjusted based on the predefined rules and criteria for publication, to be included as an appendix to this document) will include items such as: 1. Does the trial have a therapeutic (or prophylactic) intent? 2. Does the active substance appear in any marketing authorisation already granted in the EU? 3. Does the indication(s) under study in this trial appear in any marketing authorisation already granted in the EU for that active substance? 4. Does the formulation(s) appear in any marketing authorisation already granted in the EU for that active substance? 5. Does the route(s) of administration appear in any marketing authorisation already granted in the EU for that active substance? 6. What is the phase of the trial? 8. Is this a low interventional trial? 9. Does the sponsor request a deferral of the publication of the registration data until the publication of the summary results (for phase I trial only). The examples above do not pre-empt any final decision on the actual rules and criteria for publication. The specific questions will be adjusted once the rules and criteria for publication have been agreed and finalised.